



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,732	06/19/2000	Mark T. Keating	2323-151	6467

30096 7590 11/26/2001

GENZYME CORPORATION C/O ROTHWELL, FIGG, ERNST
& MANBECK
ROTHWELL, FIGG, ERNST & MANBECK
SUITE 701 EAST TOWER, 555 THIRTEEN STREET. N.W.
WASHINGTON, DC 20004

EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
----------	--------------

1646

DATE MAILED: 11/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/597,732

Applicant(s)
Keating et al.

Examiner
John Ulm

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 19, 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-30, 36, 37, 61, 62, and 64-67 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27, 28, 36, 37, and 64-67 is/are allowed.
- 6) ☒ Claim(s) 29, 30, 61, and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 20) ☐ Other:

Art Unit: 1646

1) Claims 27 to 30, 36, 37, 61, 62 and 64 to 67 are pending in the instant application. Claims 36, 37, 61 and 62 have been amended, claims 1 to 26, 31 to 35, 38 to 60 and 63 have been canceled and claims 64 to 67 have been added as requested by Applicant in Paper Number 2, filed 19 June of 2000.

2) The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

3) Claims 27, 28, 36, 37 and 64 to 67 are allowable as written.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting an essential element, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is the structure of the primers to be employed in the claimed method. Clearly the vast majority of compounds which are encompassed by the term "primers" would not function to achieve the stated purpose of the claimed method. Further, even if this element was limited to "a pair of nucleic acid primers" the claim would still be incomplete because most nucleic acid primers can not be employed to "amplify an exon of *KVLQTI*". This

Art Unit: 1646

claim needs to recite those structural features which distinguish a primer which is suitable for the amplification of "an exon of *KVLQTI*" from a primer which is not.

5) Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 29 and 30 provide for the use of a pair of primers for the amplification of "an exon of *KVLQTI*", but, since these claims do not set forth any steps involved in the method, it is unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6) Claims 29 and 30 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

Art Unit: 1646

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7) Claims 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by the Santana et al. publication (J. Bacteriol. 176(22):6802-6811, Nov. 1994). Claim 61 encompasses any isolated nucleic acid encoding at least 5 contiguous amino acid residues from SEQ ID NO:113. Claim 62 encompasses any isolated nucleic acid encoding at least 4 contiguous amino acid residues from SEQ ID NO:113. Figure 2 of the Santana et al. publication described an isolated nucleic acid encoding a protein identified therein as *atpB*. Amino acid residues 25 to 31 of *atpB* (VASVIVL) are the same as amino acid residues 173 to 179 of SEQ ID NO:113 of the instant application. Therefore, the instant claims encompass the isolated nucleic acid which was described by Santana et al. more than one year before the filing of the instant application. The Santana et al. publication is available against the instant application under 35 U.S.C. 102(b) because Applicant's priority document 60/019,014, filed 22 December of 1995, does not describe the amino acid sequence presented in SEQ ID NO:113 of the instant application. Applicant's earliest priority application which contains the amino acid sequence presented in SEQ ID NO:113 of the instant application is application Serial Number 08/739,383, which was filed on 29 October of 1996, more than one year after the publication date of the Santana et al. publication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Application/Control Number: 09/597,732

Page 5

Art Unit: 1646

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800